PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
20946WO		

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/EP 03/05876	03.06.2003	04.06.2002

International Patent Classification (IPC) or both national classification and IPC
C12N15/57

Applicant
DSM IP ASSETS B.V. et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.12.2003	08.09.2004

Name and mailing address of the international preliminary examining authority:	Authorized Officer
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/05876

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-30 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1). The present International Application relates to a protein hydrolysate "rich" in tripeptides whereby the tripeptides are "rich" in proline at one end of the peptide (claim 1). The protein hydrolysate is obtained by the combined action of a (proline)endoprotease and a tripeptidase.
In order to understand what might be meant by "rich", the IPEA considered the table shown on page 25 of the description.
A casein hydrolysate having been treated in combination with a tripeptidylaminopeptidase (TPAP) and a proline-specific endoprotoease (EndoPro) has a content of di- and tripeptides of 21 molar% of all peptides detected, and 38 molar% of all tripeptides detected have a carboxyterminal proline (i.e. less than 8 molar% of all peptides detected) (the Table presented on page 27 gives no indication what molar% of the tripeptides has a C-terminal-Pro).
Having regard to example 3, the content of tripeptides having a carboxyterminal proline residue in Nutramigen is of about 4 molar% of all peptides detected.

2.1). The following document is considered of being pertinent:

D1 JP2039896 (PAJ/JPO abstract).

D1 describes a process of treating soybean protein with both a proline specific endopeptidase and a dipeptidyl carboxypeptidase (DPCP). The resulting protein hydrolysate has a low-molecular peptide composition having <=1000 molecular weight.

2.2). The difference between D1 and the present application is the use of a dipeptidase instead of a tripeptidase.

No special or surprising effects could be shown which were due to the use of said tripeptidase.
Moreover, tripeptidase were known in the art, as mentioned in the description.
Therefore, the skilled person would have used a tripeptidase without the use of his inventive skill.

In consequence, an inventive step has to be denied for the present set of claims.